JAMES S. BENSON

EXECUTIVE VICE PRESIDENT, TECHNOLOGY AND REGULATORY AFFAIRS

October 20, 1999

VIA HAND DELIVERY

Dockets Management Branch
Mail Code HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Request for Extension of Comment Period for FDA Docket No. 98N-0313: Proposed Rule; Surgeons and Patient Examination Gloves; Reclassification

Dear Madam or Sir:

The Health Industry Manufacturers Association (HIMA), pursuant to 21 C.F.R. § 10.40(b)(3), hereby requests an extension of time to provide comments on the proposed rule referenced above. HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. The notice [64 Fed. Reg. 41,710 (July 30, 1999)] requires comments to be submitted to the agency by October 28, 1999. HIMA requests a 90-day extension of this comment period.

The subject of this proposed rule is the reclassification of surgeons and patient examination gloves from Class I to Class II, and the imposition of certain labeling and expiration dating requirements on such gloves. This subject is one that has not been considered previously by HIMA and it raises many complex questions. In fact, the proposed rule sets forth 12 specific questions to be addressed by commentaries.

In addition, HIMA notes that the American Society for Testing and Materials (ASTM) is currently balloting, but has not yet finalized, a powder standard for powdered surgeons and patient examination gloves. HIMA understands that ASTM has requested an extension of the comment period, so as to await completion of its powder standard. HIMA supports ASTM's extension request, because HIMA believes that ASTM's powder standard should be completed before the

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agency reaches a final decision on recommended powder limits for powdered surgeons and patient examination gloves.

Therefore, in view of the novelty and complexity of this issue, its importance to the medical device industry, and the fact that ASTM's powder standard has not yet been finalized, HIMA believes that sound public policy supports an additional 90 days to provide meaningful comment to FDA.

Respectfully Submitted,

James S. Benson
Executive Vice President, Technology and
Regulatory Affairs